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EXAMINER

CAPAN, ELIZABETH S

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/824,957

Applicant(s)

BALLARD ET AL.

Examiner

ELIZABETH S. CAPAN

Art Unit

4131

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 19-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 07/26/2004, 09/23/2004, 11/08/2004, 08/15/2004, 11/14/2005, 01/09/2006
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. The Examiner acknowledges the receipt of the preliminary amendment filed on 08/02/2004 wherein the claims were amended to include the addition of claims 23-25.
2. Claims 1-25 are pending.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-15 and 19-25, drawn to a delivery system comprising a homogenous, thermoreversible gel film, classified in class 424, subclasses 195.17 and 484.
 - II. Claims 16-18, drawn to a process for preparing a homogenous gel film delivery system, classified in class 424, subclasses 195.17 and 484.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the alginate gel films of invention I can be produced by a materially different method than that of invention II.

Because inventions I and II are distinct for the reasons noted above and the search required for each of the above inventions is not co-extensive, restriction for examination purposes as indicated is proper. It is noted that while

the searches of inventions I and II may be overlapping, there is no reason to believe that the searches would be coextensive. Burden consists not only of specific searching of classes and subclasses, but also of searching multiple databases for foreign references and literature searches. Burden also resides in the examination of independent claim sets for clarity, enablement, and double patenting issues. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. In searching Group II, the examiner will be focusing on the patentability of the process and not the product itself. Finally, the consideration for patentability is different in each case. Accordingly, a search for both groups would pose an undue burden on the Office.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the

inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Species Election if Applicant Elects the Invention of Group I

Should applicant elect the invention of group I, applicant is further required to elect from the following patentably distinct species

Species Election I

Applicant is required to elect an active substance, as disclosed in claim 2.

Species Election II

Applicant is required to elect a second film former as disclosed in claims 10 and 11.

Species Election III

Applicant is required to elect a plasticizer as disclosed in claim 11.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 8, and 9 are generic.

Species Election if Applicant Elects the Invention of Group II

Should applicant elect the invention of group II, applicant is further required to elect an active substance as disclosed in claim 17.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 16 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

During a telephone conversation with Liza Hohenschutz on January 10, 2008 a provisional election was made without traverse to prosecute the invention of group I, claims 1-15 and 19-25. Further species elections were made without traverse, designating the active substance of claim 2 as a "pharmaceutical

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agent", the second film former of claims 10 and 11 as "kappa carrageenan", and the plasticizer of claim 11 as "glycerin." Affirmation of this election must be made by applicant in replying to this Office action. Claims 16-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria

for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112.

Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Response to Applicant's Election

4. The Examiner acknowledges Applicants' election without traverse of Group I (claims 1-15 and 19-25) on 01/10/2008. In addition, the Examiner acknowledges the election of the species of the active substance of claim 2 (a pharmaceutical agent), the election of the species of the second film former of claims 10 and 11 (kappa carrageenan), and the election of the species of the plasticizer of claim 11 (glycerin).

Withdrawn Claims

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5. Claims 16-18 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b) as being directed to the non-elected invention.

Specification

6. The disclosure is objected to because of the following informalities: Applicants' intended meaning of "hydrozylate" is unclear throughout the entire application. This appears to be an alternate spelling of "hydrosylate" or "hydrolysate". Applicants are respectfully requested to confirm the word choice for applicant's intended meaning and, if a product of hydrolysis is intended, applicant is respectfully requested to consider using one of the more common "hydrosylate" or "hydrolysate" spellings. For the purposes of this action, Examiner assumes a product of hydrolysis is intended as Applicants' meaning.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 and 19-25 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which Applicants regard as their invention in the use of "delivery system". Since "system" implies a combination of process and products, and no process steps are included in independent claim 1, Applicants' invention is unclear. Independent claim 1 recites various embodiments, but does not recite the proximity of these embodiments with regard to time and space, specifically in how they are part of the "system." Applicants are respectfully requested to consider reciting a "composition" or "delivery composition" if this is the intended invention.

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Claims 1-15 and 19-25 are rejected under 35 U.S.C. 112, second paragraph, as failing to particularly point out the subject matter of the Applicants' invention. Instant claim 1 states that the thermoreversible gel film comprises a film forming amount of a water soluble thermoreversible alginate. The metes and bounds of "thermoreversible alginate" are unclear to one of ordinary skill in the art because it is commonly known in the art that alginates often form thermo-irreversible gels. The only commonly known thermoreversible alginate gels are formed from acetylated (modified) alginates. The Applicants have not discussed the use or sole use of acetylated alginates in the specification, but rather have discussed the use of common alginates, such as sodium alginate, which have traditionally been regarded as forming thermo-irreversible gels. Applicants are respectfully requested to consider the terminology used in this claim.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 5-15, 19-21, and 23-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-6, 8-12, 17-19, and 35-37 of copending Application No. 10824919 in view of Chapdelaine et al (WO03011259) and Pearce et al (US 2003/0224090).

Although the conflicting claims are not identical, they are not patentably distinct from each other.

I. Instant Claims 1-2

Instant claim 1 is drawn to a delivery system comprising a homogenous, thermoreversible gel film comprising a film-forming amount of a water-soluble, thermoreversible alginate, an active substance, and optionally at least one of a plasticizer, a second film former, a bulking agent, and a pH controlling agent. Instant claim 2 further specifies that the active substance is a pharmaceutical agent. Copending claim 1 is drawn to a homogenous, thermoreversible gel film comprising a film-forming amount of a water-soluble, thermoreversible alginate and optionally at least one of a plasticizer, a second film former, a bulking agent, and a pH controlling agent. The difference between these applications is that instant claims require the addition of an active substance, specifically a pharmaceutical agent, whereas copending claims do not. However, Chapdelaine teaches the inclusion of an active substance, specifically a medicament which can be a pharmaceutical, in a stand alone edible film comprised of at least three film forming agents not including pullulan (Chapdelaine, claims 1, 11, and

12). Furthermore, copending "comprising" language allows for the addition of other ingredients.

II. Instant Claims 5-8

Instant claim 5 specifies that the alginate is at least 10% of the total dry weight of the film formers. Copending claim 5 also specifies that the alginate is at least 10% of the total amount of film formers in the gel. Although copending claim does not specify dry weight, "total amount" is a general term which can encompass the species of total dry weight. Additionally, although copending claims do not recite the additional limitations of percentages of alginates in the film as instant claims 6-8 recite, the limitations of instant claims 6-8 overlap with the range provided by copending claim 5. Furthermore, these ranges are considered optimizations, thus rendering these claims obvious over copending claim 5 (see MPEP 2144.05 I-II).

III. Instant Claim 9

Copending claim 18 teaches the use of the alginate as the only film former in the gel film.

IV. Instant Claim 10

Copending claims 5 and 19 teach the use of a second film former, which can be kappa carrageenan.

V. Instant Claim 11

Copending claim 17 recites the use of a plasticizer which can be glycerin, as well as the use of a second film former which can be kappa carrageenan and the use of a bulking agent.

VI. Instant Claims 12-15 and 19-20

Copending claims 8-11 recite the break force strengths required by instant claims 12-15. Although copending claims do not superficially recite the limitations of instant claims 19-20, instant break force strengths are a result of the components of the films. Since copending films are similar to instant films, the properties will also be similar. Furthermore, the ranges of instant claims 19-20 overlap with those specified by copending claims 8-11, and the alteration of concentrations of gel ingredients to produce desirable properties is well known in the art and is an optimization of range, thus rendering instant claims 12-15 and 19-20 obvious.

VII. Instant Claim 21

Copending claim 12 teaches a solids content of at least 50% by weight of the gel film. Although copending claim 12 does not teach the addition of a flavorant as specified in instant claim 21, Pearce teaches the incorporation of a flavoring in addition to the active substance in an orally soluble edible film (Pearce, paragraphs 0057, 0058, 0121 and claim 21), thus rendering instant claim 21 obvious.

VIII. Instant Claim 23

Copending claim 35 recites the thermoreversible gel film wherein the gel film does not contain a plasticizer.

IX. Instant Claim 24

Copending claim 36 recites a gel film consisting of a film forming amount of a water soluble thermoreversible alginate, flavorant, and water. One difference between copending and instant claims is that instant claim 24 requires the addition of an active

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substance. As discussed above, Chapdelaine teaches the addition of an active substance to a gel film. Another difference is that instant claim recites a bulking agent instead of the flavorant required by copending claim. However, it is well known in the art that many flavorants, such as corn syrup, also serve as bulking agents. Thus instant claim 24 is obvious over copending claim 36.

X. Instant Claim 25

Copending claim 37 recites a gel film consisting of a film forming amount of a water soluble thermoreversible alginate, corn syrup, and water. Instant claim 25 also recites a gel film consisting of a film forming amount of a water soluble thermoreversible alginate, an active substance, corn syrup, and water. The difference between copending and instant claims is that instant claim requires the addition of an active substance. As discussed above, Chapdelaine teaches the addition of an active substance to a gel film, thus rendering instant claim 25 obvious.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-2, 9, 12-15, and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zerbe et al (US'096) in view of Day et al (US'160) and Imre et al (HU'974).

I. **Instant Claims 1-2**

A. *Thermoreversible Alginate Gel Film with Active Agent*

Zerbe teaches a film composition which comprises water-soluble polymers (which can be sodium alginate), one or more polyalcohols, and one or more pharmaceutically active agents (column 1, lines 9-12; column 2, lines 18-24 and 37-44). Although the instant invention can be made with only an alginate and an active agent, and Zerbe's invention requires the polyalcohol, Zerbe explains that the polyalcohol is required to achieve a desired level of softness (column 3, lines 10-11). Therefore, it would be obvious to one skilled in the art to remove the requirement for a polyalcohol if softness is not important. Furthermore, the instant invention allows for the optional addition of other ingredients, such as plasticizers, which include polyalcohols. Zerbe does not teach thermoreversibility

of the polymeric film. However, some of the optional polymers in Zerbe's invention commonly produce thermoreversible films. In addition, Day teaches thermoreversible alginate films using acetylated alginates. It would have been obvious to one skilled in the art to combine the teachings of Zerbe and Day to produce a thermoreversible alginate film containing an active agent.

B. Optional additional ingredients

Zerbe also teaches the optional addition of other ingredients such as plasticizers, flavors, surfactants, sweeteners, and other excipients. Although Zerbe does not expressly teach the addition of a second film former, bulking agents, or pH controlling agents, Imre teaches gelled honey which contains two film-forming agents (sodium alginate and carrageenan), a bulking agent (honey contains sugars which can serve as bulking agents), and a pH controlling agent or buffer (English abstract). Thus it would have been obvious to combine the teachings of Zerbe, Day, and Imre to include optional additional ingredients in a thermoreversible alginate film. Motivation to use a bulking agent could be to reduce "slimy" texture (Pearce, page 2, paragraph [0035]). Motivation to use a pH controlling agent comes from the fact that low pH can interfere with film properties (Pearce, page 3, paragraph [0058]), especially in the case of using kappa carrageenan as a second film former (Glicksman, page 222, paragraph two). Motivation to use plasticizers is provided because they improve flexibility and reduce brittleness (Pearce, page 3, paragraph [0044]).

II. Instant Claim 9

Zerbe teaches that the polymers can be used either alone or in mixtures (column 2, lines 41-42), thus indicating that a film composition with only alginate as the film former is obvious to one skilled in the art over the teachings of Zerbe.

III. Instant Claims 12-15, 19-20

Zerbe does not expressly describe the strength of the gel film compositions, however, Day discusses the increased flexibility and strength of acetylated alginates that form strong thermoreversible gels (column 2, lines 38-40) and Virgalitto teaches that the choice of materials to make the film is dependent on the desired strength of the film and further asserts that the gel films are of sufficient mechanical strength to be handled without special precautions. Thus it would be obvious for one of ordinary skill in the art to create gel films with substantial strength using alginates (and also alginates in combination with other strong film formers such as carrageenans) in order to create films that can survive handling and storage. Additionally, the compositions Zerbe and Day are similar to Applicants' invention, and as such, would have similar break force strengths to those claimed in Applicants' invention. Furthermore, the high and low break force strengths claimed are inherent properties of the claimed film compositions, particularly regarding the optional addition of plasticizers. Plasticizers increase film strength and reduce breaking of gels (Pearce, page 3, paragraph [0044]; Virgalitto, page 5, third paragraph). Thus the instantly claimed break force strengths are rendered inherent and obvious.

IV. Instant Claim 21

Zerbe teaches the optional addition of other ingredients such as flavorings (column 2, lines 21-23). Zerbe does not teach solids content. Imre discloses a preparation of gelled honey with sodium alginate, carrageenan, and a buffer (English abstract). The honey itself contains fructose, a known plasticizer, as well as other sugars, which are known to serve as bulking agents and honey is also known to have flavor and therapeutic properties, making it a flavorant and an active agent in the gel. The solids are adjusted to 62% to 72% (Imre English abstract). It would be obvious to one of ordinary skill in the art to add a flavoring to the gel composition since this would improve the taste or mask a medicinal taste in cases where the film would be used orally. It would also be obvious to one of ordinary skill in the art to adjust the solids content of the gel because, as Virgalitto states, a high solids content accelerates drying of the film (page 6, 4th paragraph).

11. Claims 1-8, 10-11, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pearce et al (US PG Pub '090) in view of Day et al (US'160), Chapdelaine et al (WO'259), and Earle et al (US'962).

I. Instant Claims 1-2

A. Thermoreversible Alginate Gel Film

Pearce teaches orally soluble edible films comprised of water and a film forming agent which can be alginates, carrageenans, derivatives or combinations

thereof, and other hydrocolloids (page 1, paragraph [0026]; page 2, paragraphs [0028], [0029], and [0032]). Pearce does not teach thermoreversibility. Day teaches strong thermoreversible gels made from acetylated alginates (column 2, lines 36-40). Thus it would have been obvious to one of ordinary skill in the art to make a thermoreversible alginate gel. Motivation to use alginates is provided because other hydrocolloid film formers, such as carrageenans, are potentially harmful (Tobacman). Thermoreversibility also allows gel films to be more easily poured and cast.

B. Addition of Active Agent/Pharmaceutical

Pearce teaches that the gel film may contain additional ingredients such as a pharmaceutically active agent (page 9, paragraph [0137]). Thus it would be obvious to one of ordinary skill in the art to include an active agent, more specifically a pharmaceutical, in the gel composition, especially since doing so provides an opportunity for delivery of the active substance in the oral cavity rather than in the gastrointestinal tract.

C. Optional additional ingredients

Pearce's film may also contain other additives for plasticizing (such as glycerin), a bulk filling agent (such as microcrystalline cellulose), stabilizers (such as carrageenan), flavorings, and pharmaceutically active agents (page 3, paragraphs [0048], [0052], and [0058]; page 9, paragraph [0137]). Pearce also teaches that the gel film compositions may be a combination of more than one film former (Pearce, page 2, paragraph [0028] and [0032]). Pearce does not

teach the optional addition of a pH-controlling agent. However, Chapdelaine teaches the optional addition of a pH-controlling agent (page 6, line 22). Thus the optional addition of ingredients such as plasticizers, bulking agents, a second film former, and a pH controlling agent would have been obvious to one of ordinary skill in the art. Motivation to do so is provided above.

II. Instant Claims 3-4 and 5-8

Pearce teaches that the film forming agent comprises 10% to 90% of the dry weight of the film (page 2, paragraph [0034]. Pearce does not expressly teach a percent by weight of the dry film formers. Chapdelaine teaches that the hydrocolloid constitutes 30% to 40% of the dry weight of the film (claims 18), and further provided compositions wherein the alginate comprises 12%-31% of the dry weight of the gels (examples 1-10). In regards to the instant claims drawn to the percent of alginate among only the dry film formers, Chapdelaine also teaches a composition wherein alginate is 50% of the two hydrocolloid film formers (example 10). These prior art compositions are significantly overlapping with the ranges claimed by the instant invention. "In the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior Art' a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)." Furthermore, it would be obvious to one of ordinary skill in the art to vary the amounts of the ingredients because Virgalitto teaches variation of the amounts of the ingredients based on the desired properties of the film and the nature of the

other ingredients in the film (page 6, fifth paragraph). Additionally, these percentages are an optimization of range and "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus the ranges claimed by Applicants in the instant invention are rendered obvious.

III. **Instant Claim 10**

Pearce teaches the possible use of carrageenans as film formers and also suggest that the gel film compositions may be a combination of more than one film former (Pearce, page 2, paragraph [0028] and [0032]), but does not expressly show alginates in combination with carrageenan. Chapdelaine teaches a gel created with a combination of carrageenan and alginate as the hydrocolloid film formers (example 10), and Glicksman notes that typical carrageenan contains 60% kappa carrageenan (page 218, last paragraph). Glicksman also indicates (in Table III) that kappa carrageenan gels most strongly with potassium ions, rather than lambda carrageenan (which does not gel) and iota carrageenan (which gels most strongly with calcium). Since calcium provides the best potential for alginates to gel in a thermo-irreversible manner, the choice of kappa carrageenan for the present invention to create thermoreversible gels with alginate is obvious because calcium is not required to make a strong gel network with kappa carrageenan. Another motivation for one of ordinary skill in the art to use kappa carrageenan as a second film former is due to the inherent

thermoreversibility of carrageenan gels (Macquarrie, abstract and column 1 lines 38-39). Further motivation for the choice of kappa carrageenan instead of lambda carrageenan or iota carrageenan is that kappa carrageenans form strong, firm gels (Witt, page 349, paragraph 1).

IV. Instant Claim 11

Pearce teaches the optional addition of glycerin plasticizers (Pearce, page 3, paragraph [0045]). The obviousness of the addition of kappa carrageenan is discussed above. Pearce also discusses the optional use of a bulk filling agent such as microcrystalline cellulose (Pearce, page 2, paragraph [0042]) but does not expressly discuss starch hydrolysates. Earle teaches the use of corn syrup as a bulking agent in an alginate-based edible film (column 4, lines 5-12), and corn syrup is a starch hydrolysate. Thus the gel composition with a glycerin plasticizer, kappa carrageenan as a second film former, and a bulking agent such as microcrystalline cellulose or a starch hydrolysate is rendered obvious.

V. Instant Claim 22

The choice of carrageenans as second film formers is obvious, as discussed above. The viscosity of the carrageenan solution is an inherent property that is inseparable from that solution and is therefore obvious.

VI. Instant Claim 23

Pearce allows for the optional addition of other ingredients such as plasticizers, but does not expressly teach a gel composition with alginate and without a plasticizer. Since the addition of plasticizers is optional, it would be

obvious for one of ordinary skill in art to exclude a plasticizer from the gel composition. Earle also suggests alginate compositions which do not require plasticizers (column 3, lines 65-68; and column 4, lines 1-15). The motivation to exclude a plasticizer would come from the desire to have a film that breaks rather than stretches, or is of a harder consistency, depending on the intended use of the film.

VII. Instant Claims 24-25

Pearce teaches the optional use of a bulking agent (page 2, paragraph [0035], [0041], and [0042]. One of ordinary skill in the art would have been motivated to use a bulking agent in order to improve the texture of the film; Pearce notes that using a bulking agent reduces the "slimy" texture of pullulan-free gels (page 2, paragraph [0035]). Pearce does not expressly teach the use of corn syrup. Chapdelaine teaches the use of corn syrup, though not as a bulking agent (page 7, line 15). Earle teaches the use of corn syrup as a bulking agent (column 4, lines 5-12). Since corn syrup is also a sweetener, one of ordinary skill in the art would be motivated to use corn syrup as a bulking agent because it can also sweeten the film for better taste in oral consumption.

Conclusion

12. No claims are allowed. No claims are free of the prior art.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH S. CAPAN whose telephone number is

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(571)270-5235. The examiner can normally be reached on Mon-Thurs 7:30 AM-5:00 PM, every other Friday 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. S. C./
Examiner, Art Unit 4131

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 4131